Quell™

Wearable Pain Relief
Technology

User Manual

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Chapter 1

Pain Relief with Quell

Introduction

Quell™ Wearable Pain Relief is patented non-invasive nerve stimulation technology that provides relief from chronic pain. It consists of a device and an electrode that attaches to the device. The device is worn on your upper calf, a few inches below the knee, and is controlled by a single button.

Quell provides pain relief by comfortably stimulating the nerves that carry normal, non-painful sensations to your brain, which decreases the perception of pain.

Pain relief is initiated by simply clicking a button on the device. Each therapy session is 60 minutes. After your first session, therapy will automatically restart every other hour. Pain relief usually begins within 15 minutes of the start of a therapy session and may last up to an hour following the end of a session. You have complete control and can start or end therapy anytime.

You should review this User Manual carefully. Chapter 2 shows you how to get started. Chapters 3-5 provide detailed instructions on device use. Chapter 6 describes device use during sleep. Chapter 7 offers tips for taking care of the electrodes. Chapter 8 provides information on preventing skin irritation, particularly if you have sensitive or dry skin. APPENDIX C gives answers to frequently asked questions.

If you have any questions about how to use Quell please call Quell Customer Service at 1-800-204-6577.

What You Should Have Received

Upon receiving your Quell Wearable Pain Relief System you should inspect its contents to make sure all of the following are included and undamaged.

Quell Device

Sports Band

Quell Electrode Pack*
(packaging may vary)

USB Cable

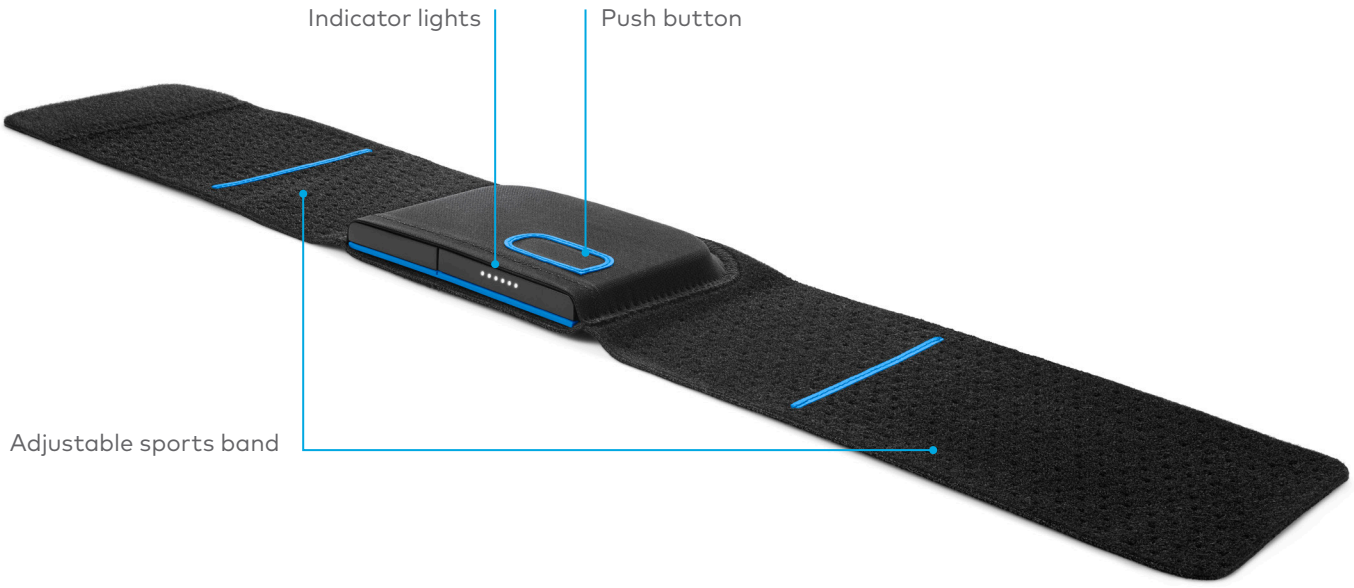
AC Adapter

Travel Bag (optional)

Quick Start Guide

* Only use electrodes manufactured by NeuroMetrix, Inc.

Device Components



Chapter 2

Getting Started

The following instructions will help you start using Quell. For additional details, please review Chapters 3-8.

These instructions are also available in video format at: **www.QuellRelief.com/user** or you can call Customer Service with any questions at 1-800-204-6577.

1. Check Battery

Click the button and check the indicator lights. The number of white lights indicates the charge remaining in the battery. A single orange light indicates the unit needs charging. If the battery needs to be recharged, use the USB cable and AC adapter.

2. Insert Device

Slide your device into the band pouch so that the button is visible inside the blue-rimmed window, with the lights facing up.

3. Attach Electrode

Remove an electrode from the bag, and snap it onto the connectors.

Carefully remove the liner, and save it for storing the electrode between uses.

4. Place Device

Place your Quell band **directly** on your upper calf approximately 1 to 2 inches below the knee of either leg. Lights should face up.

5. Calibrate

Perform this step only when using the device for the first time.

Hold the button until you see the lights running back and forth.

Every time you feel a slight buzzing sensation, click the button once. The sensation will pause each time you click the button.

When the sensation starts again, **click the button again. You will typically click the button 3-6 times.**

When the lights go off, calibration is complete. See next step to begin therapy.

6. Start Therapy

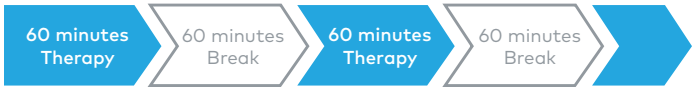
Click the button. One indicator light will blink. The sensation will increase for **2 minutes** until optimal intensity is reached. You should feel a strong but comfortable sensation under the electrode.

Decrease Intensity: Click the button to reduce intensity. Repeat if needed.

Increase Intensity: Hold button down. Intensity increases until you release the button.

Turn off: To stop therapy, click the button **four times in sequence.**

Each therapy session lasts for 60 minutes with a 60 minute break between sessions. Sessions will continue until the device is removed from the leg.



Helpful Tips

- **The entire electrode should contact the skin.**
- **Always protect the adhesive by using the liner between uses.**
- **Air-out skin after wearing the device for several hours or overnight. Device will pulse on and off for one minute as a reminder.**
- **Do not use while showering or bathing.**
- **Change the electrode every 2 weeks.**

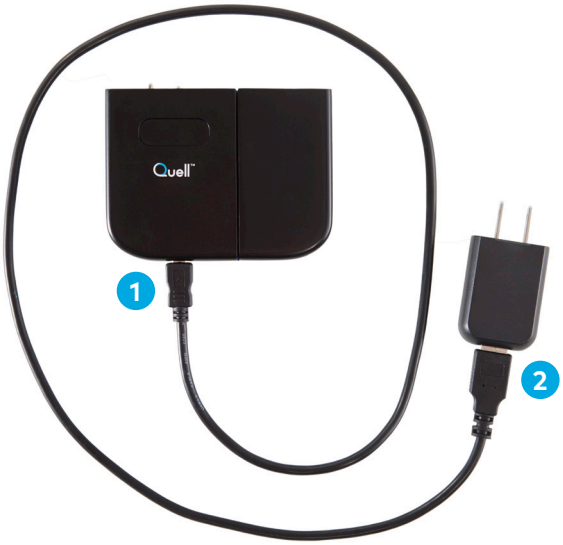
Chapter 3

Device Basics

Checking Battery

With the device in your hand, briefly click the button to check the battery. The indicator lights will flash white if the battery has sufficient charge. The number of illuminated white lights correspond to the level of battery charge. Five white lights indicate a fully charged battery. If indicator light flashes orange, the battery needs to be recharged (see below for charging instructions).

Charging Battery



A fully charged battery can provide up to 40 hours of therapy.

To charge the battery:

1. Plug the USB cable into the micro-USB port on the side of the device.
2. Plug the other end of the cable into the AC Adapter. The cable should not be plugged into a computer USB port for charging.

The AC Adapter should then be **plugged into a standard electrical outlet**. The white indicator lights on the device will show that the device is charging. The number of lights shown will increase as the battery charges. When the battery is fully charged, all 5 lights will be lit for a short time and then all the lights will turn off. It will take approximately 3 hours to charge an empty battery. When the battery is fully charged, unplug the cable from the device.

If the orange light blinks while device is connected to the outlet, charging has failed.

If the battery is too low to start a therapy session, you can charge the device for approximately 20 minutes to provide enough battery life for one therapy session. To confirm, disconnect the USB cable from the device and briefly click the button. If at least 1 white indicator light flashes, battery has enough charge for one therapy session. If the orange light flashes, reconnect the USB cable and continue charging.

Do not use your device with the USB cable connected.

Attaching Electrode

You will need to attach a new electrode prior to first use of the device and on average every 2 weeks thereafter (can be extended up to 3 days if a new electrode is not available). You should reseal the pouch if it contains an electrode. To attach an electrode, snap the electrode into the two connectors as shown below.

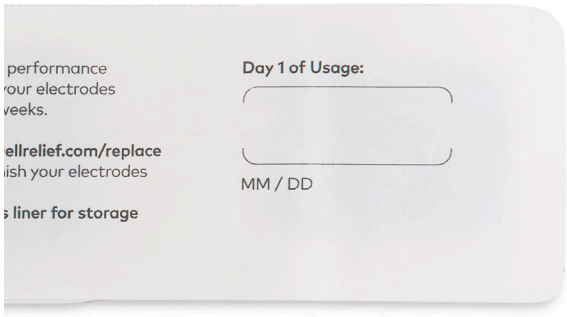
Only use Quell electrodes manufactured by NeuroMetrix, Inc.

1. Slide device into band pouch with lights facing up.

2. Align the snaps on the electrode to the snap connectors on the device. Insert snaps until they are securely fastened.

3. Remove the liner covering the electrode prior to placing the device on your leg. **Remember to keep the liner as it should be re-applied to protect the electrode when not in use.**

4. A white label is affixed to each electrode liner. The first time you use a new electrode, write the date on the liner. When placing liner on the electrode when it is not in use, ensure graphics on liner are facing up so that the paper side doesn't stick to the gel. The electrode should be replaced 2 weeks from this date (can be extended up to 3 days if a new electrode is not available).



Device Placement

Place the device on your upper calf about 1-2 inches below the knee. You may place on either leg. Be sure the electrode is only covering healthy skin that is not irritated and does not have cuts or other wounds. Position the device so that it is comfortable, the button is accessible, and you experience a strong yet comfortable sensation during therapy. You may position the device with the button on the inside, outside, or back of the leg. You should avoid placing one of the compartments directly over your shinbone.

If the device cannot be placed in the standard location as shown, refer to APPENDIX D for alternate site options.

Wrap the band around your leg and attach it with the Velcro®. The device should fit securely around your leg and be comfortable to wear. The electrode should make smooth contact with the skin. If there is buckling of the electrode, smooth the electrode and re-secure the band. **It is important that all four electrode pads are in contact with your skin.** If the pads are only partially on the skin, then the stimulation may feel uncomfortable.

The band was designed to stretch and fit most legs. If you can't get it to fit, contact Customer Service.

Chapter 4

Calibration

Before you begin using your device for the first time you will need to calibrate. You should also recalibrate your device if you are no longer experiencing pain relief. **Otherwise you do not need to recalibrate your device**, including when you switch electrodes and alternate legs.

You should carry out the calibration process in a quiet area without distractions and while sitting or standing. Make sure you are using a new electrode and that your leg is not recumbent when you calibrate your device.

1. Snap a new electrode onto the connectors.

2. Carefully remove liner and **place your Quell band directly on your upper calf** approximately 1 to 2 inches below knee of either leg. Lights should face up.

3. **Hold the button** until you see the lights running back and forth then release the button.

   Every time you feel a slight buzzing sensation, click the button once. The sensation will pause each time you click the button.

   When the sensation starts again, click the button again. **You will typically click the button 3-6 times.**

   When the lights go off, calibration is complete. If you need to halt the calibration process at any point just click the button 4 times in sequence.

Device is calibrated for a single person and should not be shared.

Chapter 5

Pain Therapy

During a therapy session, the device will comfortably stimulate the nerves in your leg to provide pain relief. Each therapy session lasts 60 minutes, and a new session will automatically restart every other hour. If you prefer not to have automatic restart turned on, consult APPENDIX E to learn how to turn it off.

To maximize pain relief, you should feel a strong but comfortable sensation. The intensity that you will require is estimated based on your device calibration. However, because of differences among people, this estimated intensity may be too low and feel weak, or too high and feel uncomfortable. In either case, you should adjust the intensity as described on page 12. The greatest pain relief will be obtained when you set the intensity to the highest level that is also comfortable. The device will remember changes to the intensity and you should not need to adjust often. Please follow the steps on the following pages for a therapy session.

Preparing for Therapy Session

Before starting a therapy session make sure you have an electrode attached to the device. You should also check the battery to ensure it has an adequate charge. Place the device on your leg as described in Chapter 3.

Starting Therapy Session

To start a therapy session, briefly click the button as shown in image below. One indicator light will blink white for the duration of the therapy session.

The intensity will gradually increase over the first two minutes to the intensity that was determined when you calibrated your device. This intensity will be stronger than what you experienced during calibration. You may not feel anything for the first 10-15 seconds, however, the blinking white light indicates the device is functioning properly. Therapy will continue for 60 minutes. You may feel a strong sensation at first but it will typically fade to a comfortable level after a couple of minutes. If the sensation is uncomfortable or painful, you should decrease the intensity as described in the next section.

Once your therapy session has begun, you may cover the device with your clothing. You should be careful not to dislodge the device and electrode when covering with clothing. It is best to wear loose fitting clothing so that you can access the device. You may go about your normal activities during a therapy session. Do not shower, bathe or swim with the device on your leg.

Adjusting Intensity During Therapy Session

Frequent adjustments should not be necessary; however, if the sensation is not strong, if it feels uncomfortable, or your calf muscle is twitching, please follow the instructions below:

Decrease Intensity: Click the button. Each click decreases intensity. Lights will indicate that intensity has decreased.

Increase Intensity: Hold button down. Intensity increases until you release the button. Lights will indicate intensity is being increased while button is held.

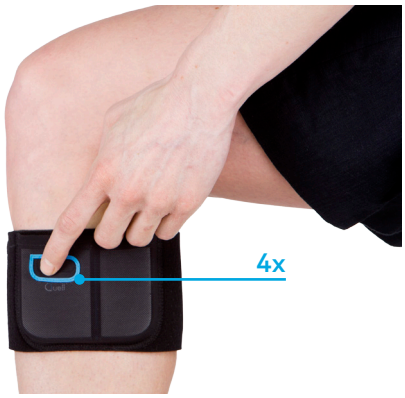
You may adjust the intensity at any time during a therapy session.

Maximum pain relief will be obtained at the highest intensity that is also comfortable.

Ending Therapy Session

Therapy sessions will run automatically 60 minutes on then 60 minutes off unless you manually turn off therapy during a session.

To manually stop therapy during a session, click the button four times in sequence. **You should not remove the device while it is stimulating,** so make sure that the indicator light is not blinking white before removing the device and electrode from your leg otherwise you may experience an uncomfortable sensation when you touch the electrode.



After completing a therapy session, you may either leave the device on your leg or remove it. If you remove the device, be careful not to damage the electrode and remember to reapply the liner (see page 14 for instructions on removing electrode).

If you leave the device on your leg for long periods of time, you should check your skin frequently to make sure that it does not get irritated. Chapter 8 provides information on skin care.

If a problem arises during a therapy session, stimulation will stop and the indicator light will blink orange for 2 minutes. Refer to APPENDIX B for troubleshooting assistance.

Air-out skin after wearing several hours or overnight; device will pulse on and off for 1 minute as a reminder.

Chapter 6

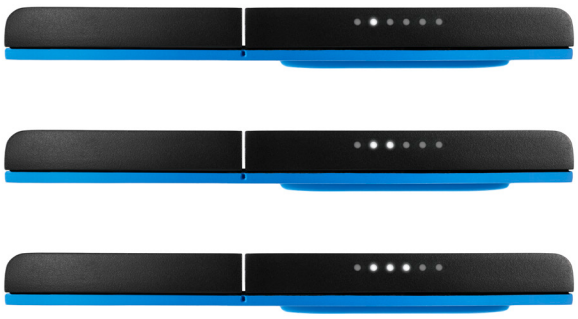
Overnight Therapy

You may use Quell at bedtime and throughout the night.

Before going to sleep, make sure the device is placed securely and comfortably around your leg. Start a therapy session by briefly clicking the button. This first therapy session will stimulate at your regular intensity level. Subsequent therapy sessions will start automatically every other hour throughout the night. If you are asleep during these sessions, the device will automatically lower the intensity. The light will blink white at a lower intensity during these sleep sessions.

Changing Sleep Settings

If the automatically lowered intensity for sleep is not ideal for you, you may change the setting. To access the setting, make sure that the device is on your leg and that the therapy session is not running (no lights are on). Then, double tap the device outside of the blue oval. You should see 1, 2, or 3 lights come on in response to your double-tap; these lights correspond to your current overnight setting. Single tap to toggle between settings. When the desired setting is shown, wait for the lights to go off and your new setting has been saved. To start a therapy session click the button once.



1 light: Bedtime Only
Therapy only while falling asleep.

2 lights: Gentle Overnight
Overnight therapy at reduced intensity.

3 lights: Full Power
Overnight therapy at daytime intensity.

Air-out skin after wearing Quell overnight.

If you have concerns about the amount or quality of your sleep, please discuss with your doctor.

Chapter 7

Electrodes

The electrodes are designed to operate consistently for at least 2 weeks (can be extended up to 3 days if a new electrode is not available). With repeated use, the electrode gel may peel a little and dry out thereby losing its stickiness, but the electrode is still usable.

Electrode Removal

You should be careful not to damage the electrode when you remove it from your upper calf area. Slowly peel the electrode from your skin, while making sure that each of the gel pads does not separate from the electrode. Avoid touching the gel with your fingers as that can damage the gel and decrease the life of the electrode. After removal of the electrode you should cover it with the liner.

If you have difficulty removing the electrode, refer to Chapter 8 for tips on skin care to ease electrode removal. Do not remove the device while therapy is running.

Electrode Storage

Electrodes should always be stored with the liner covering the gel pads. Place the liner with graphic side up so the paper does not stick to the gel. You may snap the electrode into the device for convenient storage. Electrodes should be stored at room temperature out of direct sunlight.

Electrode Replacement

The electrode should be replaced prior to two weeks if stimulation becomes painful despite positioning the device so that the entire electrode is making smooth contact with the skin. You can order electrodes at **www.quellrelief.com/replace**.

Chapter 8

Skin Care

Quell works by electrically stimulating your sensory nerves through your skin. Some people have dry or sensitive skin, and it is important to regularly monitor your skin where it contacts the electrode to ensure that skin irritation does not occur. If your skin becomes irritated, using the device may be uncomfortable. There are some simple things you can do to take care of your skin while using Quell.

Never use the device on open wounds or rashes or over swollen, red, infected, or inflamed skin.

Prevent Skin Irritation

Air-out Skin

Air-out skin after several hours of use during the day or after overnight use.

If you have sensitive skin, you may also consider the following:

Start Slow

Limit the time the device is on your skin to 3-4 hours per day in the first week. If you do not experience irritation you may increase use while closely monitoring your skin.

Use Skin Protectant

Apply a skin protectant before placing the device on your leg. Skin protectants are available as wipes, swabs, or sprays. They are safe and may reduce the likelihood of irritation. They also increase adhesion of the electrode to your skin.

Protectants that work well include:

- 3M Cavilon™ No Sting Barrier Film
- Smith & Nephew SKIN-PREP®
- Smith & Nephew No-Sting SKIN-PREP®
- Coloplast Prep™ Protective Skin Barrier

These products are available online.

Check for Skin Irritation

Check for signs of irritation, including:

- Skin itches while device is on the skin or after removal
- Skin is red where it contacted electrode
- Raised or reddened hair follicles

If skin irritation develops then you should not place the device over the irritated area until it completely heals. You may apply a topical steroid cream to help accelerate healing and reduce irritation. You may also place the device on the other leg or use different locations as shown in APPENDIX D.

If you experience skin irritation, then you should limit device use to 3-4 hours per day for a week to make sure that further irritation does not occur.

Chapter 9

Using the Mobile App

Download the App

The Quell App is optional and not required for the use of the device. From your mobile device search for "Quell Relief" by NeuroMetrix, Inc. and download the app. Before proceeding, make sure that Bluetooth® is enabled on your mobile device.

Download on the App Store

Install the App and Connect to Your Quell Device

After downloading the app, tap the Quell icon on your mobile device to start the app.

1. Tap the Start button at the bottom of your screen
2. Watch the brief introductory video, and tap Continue when done
3. Find the two-digit code on the back of your Quell device, then tap Pair on your mobile device
4. Enter the two digit code on your mobile device

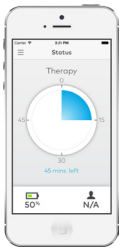
5. The app will automatically connect to your mobile device and the Success screen will appear. If you have trouble connecting, check that your Quell device has battery power by clicking the button on the Quell device and/or that your Bluetooth is enabled on your mobile device. If a minimum of one of the white LED's lights up, your Quell device has sufficient power to proceed.
6. The app will ask for permission to access your location while using the app. This is used to automate features based on the time of day.

Using the App

Time to Calibrate Your Device

This message will appear if your Quell device has not yet been calibrated. Refer to the Quick Start Guide that came with your device.

Dashboard Screen

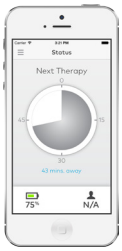


Therapy

Therapy is delivered every other hour. When Quell is delivering therapeutic stimulation, the app will display the remaining time in the one-hour therapy session.

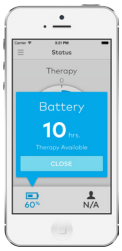
Charging

This screen shows when device is charging. Please note that your Quell device can only be charged when off your leg.



Next Therapy

If Auto Restart mode is activated, the countdown will tell you how much time until therapy automatically restarts. You can always restart therapy at any time by clicking the button on your Quell device.



Battery Check Icon

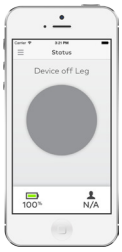
Tap the Battery icon to verify charge status of your Quell device and estimated number of therapy sessions remaining before you need to recharge your Quell device.

Ready for Therapy

Device is on the leg, but not activated. Click the button on your Quell device to begin therapy.

User Icon

Tap the User icon to see a dashboard of current activity. This shows how many therapy sessions you had today, the number of hours you spent in bed last night and your sleep quality last night.



Device Off Leg

Indicates that your Quell device is not on your leg or that the electrode is not securely attached.

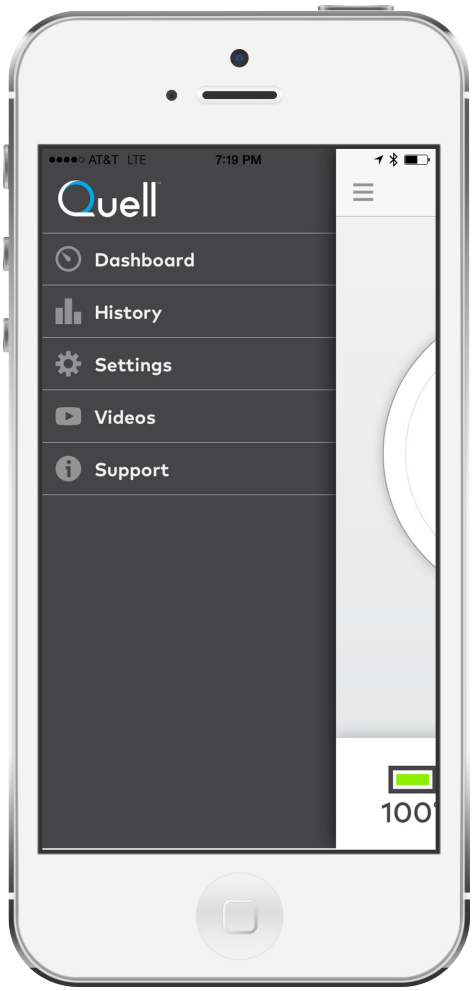
Day and Night Screens

The screens on the app will automatically adjust to night mode after dark to help in readability.

This feature is controlled by Location Services on your phone. If you choose to not allow this setting, night mode will change at 8:00 PM.

Menu

Tap the menu icon in the upper left corner of the app to access the main menu.



Dashboard

Brings you back to the Dashboard Screen.

History

Shows you therapy and sleep trends over last day, week and month. Please note that the app will display "come back in 24 hours" until it has captured enough data to report. You can tap the Therapy Icon and Sleep Icon to toggle back and forth between history screens. Please note that the sleep history screen always displays in night mode.

Videos

When your mobile device's wifi is turned on, you can access helpful how-to videos that walk your through common procedures including calibrating your Quell device, pairing with your mobile device and much more.

Settings

On the settings menu, you can turn auto restart on and off, change the sleep mode and un-pair.

- **Auto Restart**
  If Auto Restart is selected (default setting), your Quell device will automatically start therapy every other hour as long as device is on your leg. If Auto Restart is off, therapy will only initiate when you click the button on your Quell device.
- **Sleep Mode**
  The default setting is Gentle Overnight, where therapy is at a lower intensity as to not disrupt sleep. With the Bedtime-Only setting, therapy will only be delivered one time, when you first go to bed. With Full Power, therapy continues to be delivered throughout the night at the same level as during the day.
- **Pairing**
  You can use this menu to un-pair your mobile device from your Quell device. You use this if you want to pair your mobile device with a different Quell device. Tap the red button to un-pair.

Chapter 10

Maintenance, Safety, and Service

Maintenance

Contact your supplier if the device requires service.

Cleaning Device

Use a damp cloth moistened to clean the exterior of the device. Do not use any other cleaning solutions since they may damage the case. Never immerse the device in water or other liquids.

Cleaning Band

Remove device before washing the band. Handwash band with a gentle detergent and let it air dry.

Device Storage

When device is not in use store it in a dry location away from direct sunlight.

Disposal

Used electrodes should be disposed of in normal trash receptacles. Dispose of the device according to national, state, and local regulations as the device contains a Lithium-Ion battery.

Limited Warranty

NeuroMetrix, Inc. manufactures its hardware products in accordance with industry standard practices. NeuroMetrix warrants the Quell device to be free from defects in materials and workmanship at the time of shipment. The warranty term is two years beginning on the date of shipment from the manufacturer, as further described in the following text.

This warranty does not cover damage due to external causes, including accident, abuse, misuse, problems with electrical power, usage not in accordance with product instructions, failure to perform required maintenance, and problems caused by use of parts or components not supplied by NeuroMetrix. This warranty does not apply to any product repaired or altered by anyone other than NeuroMetrix or an authorized NeuroMetrix representative.

NeuroMetrix will repair or replace products that are shown to be other than as warranted above and covered under this limited warranty that are returned to NeuroMetrix under a NeuroMetrix issued Return Material Authorization (RMA) Number. To initiate a return contact Customer Service at 1-800-204-6577.

All parts removed from repaired products will become the property of NeuroMetrix. If NeuroMetrix repairs or replaces a product, the original warranty is not extended.

NEUROMETRIX MAKES NO EXPRESS OR IMPLIED WARRANTIES OR REPRESENTATIONS BEYOND THOSE STATED IN THIS WARRANTY STATEMENT. NEUROMETRIX DISCLAIMS ALL OTHER WARRANTIES AND REPRESENTATIONS, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

NEUROMETRIX'S OBLIGATIONS FOR ANY FAILURE OF A PRODUCT TO BE AS WARRANTED ARE LIMITED TO, AT NEUROMETRIX OPTION, REPAIR OR REPLACEMENT OF THE PRODUCTS SET FORTH IN THIS WARRANTY STATEMENT.

UNDER NO CIRCUMSTANCES WILL NEUROMETRIX BE LIABLE FOR ACTUAL OR CLAIMED DEFECTS IN ANY PRODUCT BEYOND THE REMEDIES SET FORTH IN THIS WARRANTY STATEMENT. IN NO EVENT SHALL NEUROMETRIX BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT REGARDLESS OF THE LEGAL THEORY UPON WHICH SUCH CLAIM IS BASED AND EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF.

APPENDIX A

Indicator Lights

Indicator Light Status	Explanation
Single Blinking White	Therapy session in progress
Single Blinking Orange	Battery needs charging, or Error
Waterfall White (lights running back and forth)	Calibration in progress
1 White Light	Adequate battery charge
2, 3, or 4 White Lights	The number of illuminated white lights correspond to the level of battery charge. The higher the number the closer it is to being fully charged
5 White Lights	Fully Charged battery

APPENDIX B

Troubleshooting

Calibration

I cannot start the calibration procedure (lights are not running waterfall motion).
Make sure the device and electrode are properly placed on the leg and the liner has been removed. Click and hold the button down for at least 5 seconds until you see the white waterfall pattern.

I am trying to calibrate, but I do not feel anything.
It may take 20-30 seconds to first feel a sensation.

When I enter calibration I see the waterfall lights briefly but then they turn off.
Make sure your leg is not recumbent when entering calibration. Try to enter calibration mode while sitting or standing.

Therapy

Make sure you initiate therapy only after the device and electrode are properly placed on the calf ( ).

When I start therapy by clicking the button once, all I see is a single blink of an orange light.
Recharge battery.

When I start therapy the light blinks white once and stops.
Calibrate device.

I am not getting pain relief.
Make sure you feel a strong but comfortable sensation. Either increase the intensity by clicking and holding the button or calibrate the device again.

Therapy stopped and the light is blinking orange.
A blinking orange light typically indicates poor contact between the electrode and the skin. This may occur because the device is not securely placed on the leg or because the electrode is dry. Check that the electrode is snapped in, the electrode is in complete contact with the skin and start therapy again. If the problem recurs, remove the device and inspect the electrode. Place the device back on the leg and restart the therapy session. If the problem persists, then replace the electrode.

The light is blinking white but I do not feel anything.
Wait until therapy has run for at least 2 minutes. If, after 2 minutes, you still cannot feel anything, the intensity is too low. Click and hold the button to increase the intensity until you have a strong but comfortable sensation. Alternatively, calibrate the device again.

What should I do if therapy stings or feels uncomfortable?
Turn off the device by clicking button 4 times. Remove the device and inspect the electrode. If your skin is dry then consider using skin moisturizer. Place the device and electrode back on your leg, making sure that there is complete contact between the electrode and the skin. If the discomfort persists then replace the electrode.

What should I do if I get leg cramps under the device?
You should lower the intensity by briefly clicking the button. Repeat as needed.

Electrode Care

The gel sticks to my skin when I remove the electrode.
If the gel is coming off the electrode then use a light lotion 30 minutes prior to therapy which should help.

The gel is dry and losing its stickiness.
The electrodes should last 2 weeks. Be sure to store electrodes properly between uses as described in Chapter 7.

The gel on my electrode is coming off.
The electrode should still function and can be used as long as the stimulation feels comfortable and the device does not repeatedly blink orange during therapy sessions.

Skin Care

My skin is irritated (redness or rash) or itches after I remove the device.
Skin irritation may occur. The skin should be aired-out after wearing for 4 hours and after overnight use by removing the device and electrode from the leg. Consider using skin moisturizer if your skin is dry.

APPENDIX C

Frequently Asked Questions

What should therapy feel like?
You should feel a vibrating or light pressure sensation. You may reduce the intensity if it feels uncomfortable.

How often can I use Quell?
You may start a therapy session whenever you need pain relief. However, it is best to wait one hour between sessions.

When do I need to calibrate my device?
You must calibrate the device before first use. You may repeat calibration if pain relief has diminished.

Do I need to calibrate the device before each therapy session?
No. Once your device is calibrated you do not need to calibrate it again unless pain relief has diminished.

Do I need to recalibrate when I switch legs?
No.

If I have foot pain, should I position the device closer to my foot?
No, you should position the device on your upper calf 1-2 inches below the knee as described in Chapter 3.

Can I place the device on my arms or lower back?
No.

Will pain relief start immediately after I click the button?
Pain relief usually starts within 15 minutes.

Will pain relief continue beyond the end of the therapy session?
Pain relief may last up to an hour after the session ends.

How often do I need to change the electrode?
Every 2 weeks (can be extended up to 3 days if a new electrode is not available).

Can I use my device while showering or bathing?
No.

Are there side effects?
No. You may experience some mild skin irritation under the electrodes with prolonged use.

Can I use it with pain medications?
Speak to your doctor about your pain medication use in conjunction with Quell.

Can multiple people share the device?
No. The device is calibrated for one person and should not be shared.

Can I use Quell while sleeping?
Yes.

What does Quell do while I am sleeping?
It starts 60 minute therapy sessions every other hour throughout the night to help control your pain. See Chapter 6 for more information on device settings overnight.

Do I need to set up Quell differently for sleep use?
No, but there are 3 sleep setting options (see Chapter 6).

What if I only want a single 60 minute therapy session when going to sleep?
Set the sleep setting to Bedtime Only (see Chapter 6).

What should I do before going to sleep?
Make sure the device is securely and comfortably placed around your leg. Start the first therapy session by briefly clicking the button.

Will wearing Quell overnight irritate my skin?
You should air-out your skin every morning.

Can I use Quell every night?
Yes.

APPENDIX D

Alternate Placement Sites

If your Quell device cannot be placed at its usual location just below the knee, such as due to a wound or skin irritation, then it may be positioned at one of the following alternate sites:

At mid-calf

Above the knee on the lower thigh

You should calibrate the device at the new site before initiating therapy.

APPENDIX E

Automatic Restart

You may toggle the automatic therapy restart from on to off or vice versa. With the device in your hand, without an electrode attached, click and hold the button for at least 10 seconds, and you will see either one or 5 white lights. One light means that automatic restart is now off; 5 white lights mean that automatic restart is now on. Note that automatic restart must be on in order to use and change the overnight settings (described in Chapter 6).

Automatic restart is now off

Automatic restart is now on

APPENDIX F

Technical Specifications

Output	
Waveform	Biphasic with alternating leading phase, symmetrical, rectangular
Regulated Current or Voltage	Current
Net Charge per Pulse	0±1 µC into 500Ω load
Maximum Output Voltage (±10%)	100 V
Maximum Output Current (<1KΩ load) (±10%)	100 mA
Pulse Duration (±4%)	200 - 400 µsec
Pulse Frequency (±4%)	60-100 Hz, randomly varying
Pulse Pattern	Continuous
Maximum Phase Charge	20 µC
Maximum Current Density	0.71 mA/cm^2 into 500Ω load
Maximum Average Current	4 mA into 500Ω load
Maximum Average Power Density	7 mW/cm^2 into 500Ω load

Output Trips	
No Load	Device not connected to patient
Insufficient Charge	Delivered charge below target
Over Load	Delivered charge above target
Short Circuit	Low impedance
Electrode Peeling	Electrode dislodging from skin

Therapy Session	
Timer	60 minutes
Start Therapy	Click button once
Stop Therapy	Click button 4 times
Manual Intensity Increase/Decrease	Increase +1.25% per second, decrease -5%
Habituation Compensation	Adaptive stepwise increase in intensity of during session

Electrode	
Type	Self-adhering, single-patient use, multiple applications
Materials	Mylar substrate, silver electrode pads
Number of Electrodes	2, outer electrode area 28 cm^2, inner electrode area 33 cm^2
Connector	Medical snap (male)
Dimensions	0.2 cm x 5.3 cm x 28.3 cm (exterior)

Power	
Source	Permanent rechargeable battery
Battery Type	Rechargeable 3.7V Lithium-Ion battery
Charging Source	AC line adapter
Line Current Isolation	Patient disconnected when charging
Patient Leakage Current, DC	< 10 µA
Patient Leakage Current, Enclosure	< 100 µA

Physical	
Dimensions	98 mm x 74 mm x 11 mm
Weight (without straps)	62 g

Environmental	
Operating Temperature Range	10° C to 40° C
Atmospheric Pressure Range	50 kPa to 106 kPa
Relative Humidity Range	30% to 75%
Transport and Storage Temperature Range	-40° C to 50° C
Atmospheric Pressure Range	50 kPa to 106 kPa
Relative Humidity Range	10% to 90%

Guidance Documents & Standards	
FDA	Draft Guidance for Industry and Staff: Class II Special Control Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief (April 5, 2010)
IEC	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62304

APPENDIX G

Precautions & Warnings

Indications

Quell is intended for use as a transcutaneous electrical nerve stimulation device for the symptomatic relief and management of chronic intractable pain.

The device may be used during sleep. The device is labeled for use only with compatible NeuroMetrix electrodes.

Contraindications

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Precautions

- Transcutaneous electrical nerve stimulation is not effective for pain of central origin, including headache.
- Transcutaneous electrical nerve stimulation is not a substitute for pain medications and other pain management therapies.
- Transcutaneous electrical nerve stimulation devices have no curative value.
- Transcutaneous electrical nerve stimulation is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- The long-term effects of electrical stimulation are unknown.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- The safety of electrical stimulation during pregnancy has not been established.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- Use caution if stimulation is applied over the menstruating or pregnant uterus.
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep this device out of the reach of children.
- Use this device only with electrodes and accessories recommended by the manufacturer.

Adverse Reactions

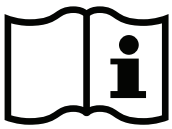
- You may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.
- You may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
- You should stop using the device and should consult with your physician if you experience adverse reactions from the device.

Warnings

- If you are in the care of a physician, consult with your physician before using this device.
- If you have had medical or physical treatment for your pain, consult with your physician before using this device.
- If your pain does not improve, becomes more than mild, or continues for more than 5 days, stop using the device and consult with your physician.
- Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal.
- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- Do not apply stimulation when in the bath or shower.
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
- Consult with your physician before using this device, because it may cause lethal rhythm disturbances to the heart in susceptible individuals.
- Apply stimulation only to normal, intact, clean, healthy skin.
- No modification of this device is allowed.
- Do not use the device on children.

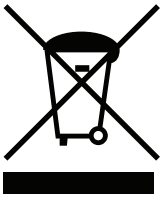
APPENDIX H

Symbols



User Manual/device labeling

Type BF Applied Part



WEEE (Waste Electronic and Electrical Equipment) symbol in accordance with council directive 2002/96/EC

MN:

Abbreviation for model number

APPENDIX I

Electromagnetic Compatibility Declaration

Quell is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions; CISPR 11	Group 1	Quell uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions; CISPR 11	Class B	Quell is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Electrostatic Discharge Immunity (ESD); IEC 61000-4-2	±6kV contact; ±8kV air	Floors should be wood, concrete or ceramic tile.
Radiated RF; IEC 61000-4-3	3 V/m; 80 MHz to 2.5 GHz	3 V/m compliance level

APPENDIX J

FCC and IC

This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

1. This device may not cause interference, and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

FCC RF Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter meets both portable and mobile limits as demonstrated in the RF Exposure Analysis. The Bluegiga BLE Bluetooth Module contains Transmitter Module:

FCC ID: QOQBLE113
IC: 5123A-BGTBLE113

APPENDIX K

Bluetooth®

The Bluetooth word mark and logos are owned by the Bluetooth SIG, Inc. and any use of such marks by NeuroMetrix, Inc. is under license.

Communication between the Quell Device and the Smartphone is via Bluetooth.

Disabling Bluetooth

While all sensitive data transmission is encrypted, Bluetooth functionality can be turned off for increased privacy. If Bluetooth is disabled, then the Quell Relief App will not function, but all other functions of the Quell device will operate normally. To turn off Bluetooth:

1. Plug the Quell device into the charger/wall outlet,
2. Click and hold the button on the Quell Device for approximately 10 seconds until the one orange and one white LED flashes.
3. The Bluetooth module is now disabled.

To reactivate Bluetooth functionality, repeat the above steps. All six LED's should be illuminated.

Bluetooth Specifications	
Bluetooth Module:	Bluegiga BLE 113 Bluetooth® Module with Bluetooth® 4.0 low energy radio
Transmit Power:	+0 dBm
Receiver Sensitivity:	-93 dBm
FCC Rules:	Part 15C
Frequency Range:	2402.0 - 2480.0
Output Watts:	0.0011
Security:	Encryption

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Quell User Guide
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